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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,709	09/18/2000	Hiroyuki Fujita	001200	4404

7590 09/07/2004

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EXAMINER	
GUPTA, ANISH	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/663,709	FUJITA, HIROYUKI	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Withdrawn Rejections:

Claim Rejections - 35 USC § 112

The rejection of claims 1-4 and 7-8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn.

The rejection of claims 1-4 are 7-8, rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is hereby withdrawn.

Maintained Rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3 and 7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama et al. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to a angiotensin converting enzyme inhibitor.

Applicants argue that the reference of Yokoyama et al. does not comprise polypeptides that have a molecular weight of at least 500 daltons. Accordingly, the present invention differs from the claimed invention the polypeptides having molecular weight of at least 5000 is not present. Further, "the present invention has different and extremely superior effect of improving bitterness and bad flavor characteristic to purified peptides, by containing at most 10% by weight of polypeptides having a molecular weight of at least 5000." Finally, it is argued that the composition comprise solvents that cannot be used in processing food, such as acetornitrle and trifluoroacetic acid. "Yokoyama et al. merely reports that the ptpeides having ACE inhibitory activity contained in thermolysin digest of dried bonito were identified, and neither describes nor suggest using the peptides as a food."

Applicant's arguments filed 6-9-04 have been fully considered but they are not persuasive.

Applicants state that their product has superior results since it does not have bitter taste. As stated in the previous office actions, the reference teaches that "[t]hermolysin, as well as chymotrypsin or trypsin digest had no **bitter taste [emphasis added] but had a good taste characteristic of dried bonito.**" (See page 1542 and 1544). Thus, the prior art product is similar to the claimed invention in its taste quality. By virtue of disclosing that the digest did not have a bitter taste, the reference implies that the digest was eaten. On page 1541 the reference states "protease digest of dried bonito had ACE-inhibitory activity in addition to a good taste." Furthermore, the reference states, on page 1545, the reference states "a new concept called 'functionalities of food' has been proposed; foods have nutritional function (primary function), sensory function (secondary function), and physiological function (tertiary function). The thermolysin digest of dried bonito has excellent primary, secondary, and tertiary functions, and is expected to be a physiologically

functional foodstuff having antihypertensive effects." Thus, the reference states that the dried bonito digest is "food."

Finally, with regards to the presence of polypeptides with the desired molecular weight, on page 6 of the specification, it is stated "[i]t is not suitable when a content of the polypeptide having a molecular weight of 5000 is over 10% by weight, because there are defects that hue will become yellow or brown, bitterness slightly remains to give unnatural flavor, and that aftertaste remains for a long time if the peptide I added to weak-flavored things, and further because inhibitory activity will not be improved." The reference teaches that "[t]hermolysin, as well as chymotrypsin or trypsin digest had **no** bitter taste [emphasis added] but had a good taste characteristic of dried bonito." (See page 1542 and 1544). Thus, since "no bitter taste" was present in the prior art composition, then one can conclude that the content of the polypeptide of 5000MW is less than 10%, otherwise bitter taste would be observed as discussed in the instant specification.

The rejection is maintained.

2. Claims 1, 3, 7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yasumoto (JP06298794).

The claims are drawn to a angiotensin converting enzyme inhibitor.

Applicants argue that "[i]t is well known in the art that from the same starting material subjected to a separation, the separated products will differ when the separation methods differ. Therefore, because the present invention differs form Yasumoto et al. in the separation method, it is clear that the present invention differs from an angiotensin converting enzyme inhibition peptide contention solution described in Yasumoto et al."

Applicant's arguments filed 6-9-04 have been fully considered but they are not persuasive.

The MPEP states:

> "The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

In the instant case, there is sufficient basis to establish a prima facie case of obviousness. The same source as the claimed invention is used, dried bonito. The same enzyme as claimed is used to digest the dried bonito, thymosin. Finally the same result is achieve, that is a product has little bitterness. Thus, the burden proof upon the Patent Office has been met. The applicant has not met their burden of proof to sufficiently rebut the rejection since Applicants have not provide any "evidence establishing an unobvious difference between the claimed product and the prior art product." Applicants opinion that the process might lead to different product is not sufficient to establish that the product are indeed different. The MPEP is clear when it states "it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure."

Absent any evidence to the contrary, the rejection is proper and is maintained.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

8/24/04

Anish Gupta
Patent Examiner

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
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